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REMARKS/ARGUMENTS

Claims 1, 2, 4-6, 8, 10, 11, 16, 19, and 21 have been amended. Claims 22-42 have been added. Claims 9, 17, and 18 have been canceled. Thirty-nine claims remain pending in the application: Claims 1-8, 10-16, and 19-42. Reconsideration of Claims 1-8, 10-16, and 19-21 in view of the amendments above arguments below is respectfully requested. Consideration of new claims 22-42 is likewise respectfully requested.

By way of this amendment, Applicants have made a diligent effort to place the claims in condition for allowance. However, should there remain any outstanding issues that require adverse action, it is respectfully requested that Examiner telephone the undersigned at (805) 781-2865 so that such issues may be resolved as expeditiously as possible.

Applicable law with regard to rejections  
according to 35 U.S.C § 103(a)

To establish a prima facie case of obviousness there must be some suggestion or motivation in the prior art to make the claimed invention, there must be a reasonable expectation of success, and the prior art references must teach or suggest all of the claim limitations. MPEP 2142; *In re Vaeck*, 947 F.2d 488, 20 USPQd, 1483 (Fed. Cir. 1991). Both the suggestion and the expectation of success must be founded in the prior art, and not in the Applicant's disclosure. *In re Dow Chemical Co.*, 5 USPQ2d 1529 (Fed. Cir. 1988). The mere fact that the prior art can be modified does not make the modification obvious unless the prior art taught or suggested the desirability of the modification. *In re Gordon*, 221 USPQ1125 (Fed. Cir. 1984). The patent office has the burden of establishing a prima facie case of obviousness. MPEP 2142; *In re Vaeck*, 947 F.2d 488, 20 USPQ2d, 1438 (Fed. Cir. 1991).

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Turning to the specific objections and rejections:

1. Claims 1, 3-5, 7, 14, 16, 19, and 21 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Horowitz et al. (U.S.P.N. 5,981,163) in view of Platz et al. (U.S.P.N. 6,187,572). Claims 1, 3-5, 7, 14, 16, 19, and 21 are not rendered obvious by the teachings of Horowitz et al. and Platz et al. Specifically, independent claims 1, 5, 14, and 19 recite providing "pulses of a light." However, despite the Examiner's assertion, "pulses of a light" are not taught by the '163 or '572 patents. Additionally, Applicants have further defined "pulses of a light" by amending claims 1, 5, and 19 to recited "pulses of light having a pulse duration of less than 100 ms" as found in dependent claims 2, 6, and 20.

In contrast to the "pulses of a light having a pulse duration of less than 100 ms" recited in Applicant's claims 1, 5, and 19 the '163 patent teaches illumination for intervals of 25 minutes to 90 minutes<sup>1</sup>. The '572 patent teaches illumination for intervals of "2 minutes up to a 10 minute total exposure."<sup>2</sup> As is well known in the art, light pulses are on the order of magnitude of seconds, and more preferably milliseconds *or less*, not minutes or hours as taught by Horowitz et al. and Platz et al. According to Webster's Dictionary, a pulse is defined as "a quick temporary change in electrical or wave energy." Nothing in the range of 2 minutes to 90 minutes can be considered "quick" or "temporary" as such terms are known and used in the art. Claims 1, 5, and 19 are further distinguished from the '163 and '572 patents with the recitation that the "pulses of a light" have "a pulse duration of less than 100 ms." Suitable durations of a "pulse of a

<sup>1</sup> See Examples Section, e.g. column 17, lines 66 and 67

<sup>2</sup> See Column 28, line 67 and column 29, line 1

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light" for use with the present invention is discussed on page 13, lines 4-7.

With regard to claim 14, the Examiner asserts that Platz et al. teaches "illuminating continuously for 6 hours." Platz et al. does in fact teach continuously illuminating "the contents of the bag [with UVA light] from top and bottom for 6 hours."<sup>3</sup> However, claim 14 of the present application teaches and claims "repeating the illumination of the platelet composition every 6 hours" wherein illumination is "pulses of a light having at least one wavelength within a range of 170 to 2600 nm and a fluence greater than about 0.001 J/cm<sup>2</sup>." Claim 14 of the present application teaches **REPEATING** illumination every 6 hours and not **CONTINUOUS ILLUMINATION** for 6 hours as taught by Platz et al. In this regard, claim 14 of the present application is fundamentally different in the illumination of a biological composition than Platz et al.

Assuming that the prior art references teach each of the claim limitations (which they do not), the patent office still has the burden of establishing a prima facie case of obviousness. MPEP 2142; *In re Vaack*, 947 F.2d 488, 20 USPQ2d, 1438 (Fed. Cir. 1991). In establishing a prima facie case of obviousness, there must be some suggestion or motivation in the prior art to make the claimed invention. Furthermore, both the suggestion and the expectation of success must be founded in the prior art. However, the Examiner has not pointed out where the "suggestion or motivation" in the cited references lies to combine the two references.

Therefore, the Examiner has not established a prima facie case of obviousness and Applicants respectfully request reconsideration and withdrawal of the present rejection. Independent claims 1, 5, 14, and 19 are distinguished from the cited references by at least the recitation of "pulses of a

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<sup>3</sup> See column 35, lines 37-39

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light." Independent claims 1, 5, and 19 are further distinguished from the cited references by defining the "pulses of a light" as "having a pulse duration of less than 100 ms." Claim 14 is further distinguished from the cited references for citing "repeating the illumination of the platelet composition every 6 hours" as opposed to Platz et al. which cites illuminating continuously for 6 hours. As claims 3, 4, 7, 16, and 21 depend from claims 1, 5, 14, and 19, Applicants request that the present rejection be withdrawn from all claims: 1, 3-5, 7, 14, 16, 19, and 21.

2. Claims 2, 6, 15, and 20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Horowitz et al. (U.S.P.N. 5,981,163) in view of Platz et al. (U.S.P.N. 6,187,572) and further in view of O'Dwyer et al. (U.S.P.N. 6,312,931). Claims 2, 6, 15, and 20 depend from claims 1, 5, 14, and 19. It is assumed that the Examiner maintains the same explanations of the '163 and '572 patents as set forth in paragraph 4 of the October 14, 2003 office action. The Examiner asserts that O'Dwyer et al. "teaches a spectral range and a pulse duration."

Claims 2, 6, 15, and 20 are not rendered obvious by the teachings of Horowitz et al. and Platz et al. in view of O'Dwyer et al. Claims 2, 6, 15, and 20 depend from claims 1, 5, 14, and 19 which Applicants submit are allowable based on the arguments provided hereinabove. As such, any dependent claim based on an allowable independent claim (i.e. 1, 5, 14, and 19) shall be construed to include the subject matter of such an allowable independent claim and would therefore be deemed allowable as a matter of law.<sup>4</sup>

However, to further distinguish claims 2, 6, and 20 from the cited art, Applicants have amended such claims to recite "wherein

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<sup>4</sup> See 37 CFR 1.75(c)

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said method does not include the addition of a quenching agent, photoradiation sensitizer, or albumin." The '163 patent, the '572 patent, and the '931 patent teach and claim additional steps including the addition of a "quenching agent"<sup>5</sup>, a "chemical sensitizer"<sup>6</sup>, and "albumin"<sup>7</sup>, respectively. Neither of these agents are claimed in the present application. On the contrary, the present application advantageously works without the addition of a quenching agent or chemical sensitizer (i.e. phototoxic drug) or albumin as defined by Horowitz et al., Platz et al., and O'Dwyer et al., respectively. None of the cited references (i.e. the '163 patent, the '572, and the '931 patent) teach the illumination of biological compositions without the addition of a quenching agent or chemical sensitizer or albumin (as defined hereinabove). In fact, the cited references teach away from the illumination of a biological composition without the addition of a quenching agent, a chemical sensitizer, or albumin. For example, see column 3, line 66 through column 4, line 4 of the Horowitz et al. patent:

UV treatment alone of either plasma or AHF concentrates results in a relatively high loss of coagulation factor activity under conditions which kill  $\geq 10^5$  ID<sub>50</sub> of virus; however; it has been discovered that this loss is significantly reduced (i.e. the recovery is high) when quenchers of photodynamic reactions are added prior to UV treatment.

The Platz et al. patent likewise teaches away from the present application by reference to the addition of a "radiation

<sup>5</sup> See each independent claim, e.g. claims 1, 40, and 41

<sup>6</sup> See each independent claim, e.g. claim 1

<sup>7</sup> See each independent claim, e.g. 1, 9, 10, and 18.

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**sensitizing compound".** Looking now to column 4, lines 21-26 of the '572 patent:

According to the present invention, **a radiation sensitizing chemical compound is added to a liquid suspension of infectious viruses, and the mixture is exposed to UV light or ionizing radiation. Assays of viral infectivity demonstrate the effectiveness of the compounds in inactivating the viruses, compared to radiation treatment alone.**

The teachings of Horowitz et al. and Platz et al. are in sharp contrast to the present application which advantageously provides microbe inactivation without the addition of a **quenching agent and/or a chemical radiation sensitizer.**

Horowitz et al. and Platz et al. utilize continuous light with the addition of a phototoxic drug to inactivate microorganisms. However, the use of such phototoxic drugs causes toxicity problems with certain blood components. To solve this problem, Horowitz et al. utilizes quenching agents which work as "a scavenger of free radicals"<sup>8</sup>, thus protecting platelets. The present application obviates this need for a quenching agent by inactivating microbes **with the sole use of high energy pulsed light.** The fact that Horowitz et al. specifically teaches the use of a quenching agent to protect blood components when inactivating microbes with a combination of continuous light and phototoxic drugs, **is completely contradictory to the present application.** The cited references, therefore, teach away from the present application. Applicants maintain the same objections as recited hereinabove with regard to the Examiner's reliance on the Horowitz et al. and Platz et al. patents for teaching that which is recited in the rejected claims including "pulses of light having a pulse duration of less than 100 ms."

<sup>8</sup> See column 2, line 29-30

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Additionally, Applicants maintain that the use of the Horowitz et al. and Platz et al. patents is improper since both teach the use of a chemical agent (i.e. a **quenching agent** and a **chemical radiation sensitizer**). As such, the '163 and '572 patents teach away from the principles set forth in the present application.

The O'Dwyer et al. reference is likewise misplaced as O'Dwyer et al. teaches and claims the addition of "albumin to a biologically derived composition"<sup>9</sup> for "providing methods for protecting biomolecules of interest."<sup>10</sup> As previously stated, the present application advantageously works without the addition of a chemical agent (**including a quenching agent, a chemical radiation sensitizer, and albumin**). Applicants contend that in light of the fact that all of the art relied upon by the Examiner in making the present rejection teach the addition of a chemical agent (as defined hereinabove) for the inactivation of various types of microorganisms with illumination, and do not teach that such inactivation could be successfully accomplished while maintaining the underlying biological material in the absence of such chemical agent, Applicant's method including subjecting a platelet composition to pulses of light without the addition of a chemical agent is **non-obvious**. Therefore, the teachings of the present application without the use of a chemical agent (as defined hereinabove) is **non-obvious** in light of the Horowitz et al., Platz et al., and O'Dwyer et al. patents which describe the need for such an agent.

In summary, the Examiner has failed to make a prima facie case of obviousness based on the fact that **the prior art references do NOT teach or suggest each and every claim limitation** of the rejected claims (i.e. "pulse of a light", "pulse of a light having a pulse duration of less than 100 ms,

<sup>9</sup> See column 3, lines 54-55

<sup>10</sup> See column 3, lines 33-34

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"repeating the illumination of the platelet composition every 6 hours", and "wherein said method does not include the addition of a quenching agent, photoradiation sensitizer, or albumin") as well as a lack of suggestion or motivation to combine the references. The prima facie case of non-obviousness is further refuted by evidence, as stated above, that the cited patents in fact teach away from the principles outlined in the present application.

Thus, Applicants respectfully request reconsideration and withdrawal of the present rejection directed to claims 2, 6, 15, and 20.

3. Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Horowitz et al. (U.S.P.N. 5,981,163) in view of Platz et al. (U.S.P.N. 6,187,572) and further in view of Goodrich, Jr. et al. (U.S.P.N. 6,277,337). The Examiner concluded in the office action of October 14, 2003 that "Horowitz et al. teaches the following: a method of irradiating microbes in a platelet composition, illuminating the fluid with pulses of light, and least about 2 logs." The Examiner contends that Platz et al. "discloses illuminating at 320 nm but fails to teach flowing the platelet composition." The Examiner further contends that Goodrich, Jr. et al. "teaches flowing blood compositions in an apparatus such that the treatment chamber must be at least 1% transmissive to light in order to inactivate blood components."

Claim 8 has been amended to include the limitation of claim 9. As amended, claim 8 is not rendered obvious by the teachings of Horowitz et al. and Platz et al. in view of Goodrich, Jr. et al. Applicants maintain the same objections as recited hereinabove with regard to the Examiner's reliance on the Horowitz et al. and Platz et al. patents as teaching limitations included in the rejected claims (as amended), i.e. "pulses of light having a pulse duration of less than 100 ms".



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Additionally, Applicants maintain that the use of the Horowitz et al. and Platz et al. patents is improper as both teach the use of a chemical agent (i.e. a **quenching agent** and a **chemical radiation sensitizer**). As such, the '163 and '572 patents teach away from the principles set forth in the present application.

The '377 patent is likewise misplaced as Goodrich, Jr. et al. teaches and claims "mixing an effective non-toxic amount of an endogenous **photosensitizer**" with the fluid to be exposed to photoradiation.<sup>11</sup> In the case of Goodrich, Jr. et al., the Examiner relies on a reference that is principally contradictory to the present application. As previously stated, the present application advantageously works without the addition of a chemical agent (**including a quenching agent, a chemical radiation sensitizer/photosensitizer, and albumin**). Furthermore, the teachings of the present application without the use of a chemical agent (as defined hereinabove) would be **non-obvious** in light of the Horowitz et al., Platz et al., and Goodrich, Jr. et al. patents, which describe the need for such an agent.

The Examiner has not established a prima facie case of obviousness on the basis that **the prior art references to NOT teach or suggest each and every claim limitation of the rejected claims and the absence of a suggestion or motivation to combine the cited references**. The prima facie case of non-obviousness is further refuted by evidence, as stated above, that the '163 and '572 patents in fact teach away from the principles outlined in the present application. Applicants, therefore, respectfully request reconsideration and withdrawal of the present rejection directed to claim 8.

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<sup>11</sup> See Column 4, lines 1-3

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4. Claims 9-13 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Horowitz et al. (U.S.P.N. 5,981,163 in view of Platz et al. (U.S.P.N. 6,187,572) and further in view of Goodrich, Jr. et al. (U.S.P.N. 6,277,337) and O'Dwyer et al. (U.S.P.N. 6,312,931). Applicants have cancelled claim 9. With respect to pending claims 11 and 13, the Examiner concluded in the office action of October 14, 2003 that "Horowitz et al. discloses illuminating with a fluence at 254nm such that most of the fluence is concentrated within a range of 200 to 300nm and teaches that any type of platelet concentrate can be illuminated." The Examiner further concludes that "Goodrich, Jr. et al. teaches flowing blood components past UV lights." Further, the Examiner states, "with respect to claim 10, O'Dwyer et al. teaches a pulse duration range."

Pending claims 10-13 are not rendered obvious by the teachings of Horowitz et al. and Platz et al. in view of Goodrich, Jr. et al. and O'Dwyer et al. for at least the reasons stated hereinabove. For example, claims 10-13 read on claim 8, which as amended, includes the limitation of a light treatment wherein the light treatment is "provided in pulses of light." As previously stated neither the Horowitz et al. nor the Platz et al. patents teach light treatment "provided in pulses of light." Furthermore, each of the cited references (i.e. the '163 patent, the '572 patent, the '337 patent, and the '931 patent) teach the additional limitation including the addition of a chemical additive (i.e. quenching agent, photoradiation sensitizer, or albumin).

The Examiner has not succeeded in making a prima facie case of obviousness on the basis that the prior art references do NOT teach or suggest each and every claim limitation of the rejected claims and the absence of a suggestion or motivation to combine the cited references. The prima facie case of non-obviousness is further refuted by evidence, as stated above,

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that the '163 and '572 patents in fact teach away from the principles outlined in the present application. Applicants, therefore, respectfully request reconsideration and withdrawal of the present rejection.

5. Claims 17 and 18 stand rejected under 35 U.S.C. § 102(e) as being anticipated by O'Dwyer et al. (U.S.P.N. 6,312,931). Claims 17 and 18 have been canceled herewith and therefore their rejection is now moot.

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Newly submitted Claims 21-42 are believed to be allowable because they are directed to that which is not shown or suggested in the prior art. In particular, each of the references cited by the Examiner teach the addition of a quenching agent, photoradiation sensitizer, or albumin. The newly submitted claims, however, recite the inactivation of microbes utilizing a treatment comprising "pulse of a light" without the addition of a phototoxic drug and/or molecule protecting chemical.

In view of the above, Applicants submit that Claims 1-8, 10-16, and 17-42 are now in condition for allowance, and prompt and favorable action is earnestly solicited.

Respectfully submitted,

  
FITCH, EVEN, TABIN & FLANNERY

Thomas F. Lebens  
Reg. No. 38,221

Address all correspondence to:  
FITCH, EVEN, TABIN & FLANNERY  
Suite 1600 - 120 South LaSalle Street  
Chicago, IL 60603-3406

Direct telephone inquiries to:  
Thomas F. Lebens  
805-781-2865